

§Appl. No. 09/684,883
Amdt. dated August 25, 2004
Reply to Non-Compliant Amendment, August 13, 2004

IN THE CLAIMS

This listing of claims will replace all prior versions, and listing of the claims in the application.

Listing of Claims:

Claims 1-90 (canceled)

Claim 91 (Withdrawn) An isolated polynucleotide that hybridizes under stringent conditions to either (a) a DNA sequence encoding a *Neisseria* surface protein or (b) the complement of a DNA sequence encoding a *Neisseria* surface protein, wherein said *Neisseria* surface protein:

- (i) is resistant to proteinase K, and
- (ii) has an apparent molecular weight of 22 kDa.

Claim 92 (Withdrawn) The polynucleotide of claim 91, wherein said *Neisseria* surface protein is encoded by a DNA molecule that comprises bases 200 to 667 of SEQ ID NO:1.

Claim 93 (Withdrawn) The polynucleotide of claim 92, wherein said DNA molecule comprises bases 143 to 667 of SEQ ID NO:1.

Claim 94 (Withdrawn) The polynucleotide of claim 93, wherein said DNA molecule comprises SEQ ID NO:1.

Claim 95 (Withdrawn) The polynucleotide of claim 91, wherein said *Neisseria* surface protein is encoded by a DNA molecule that comprises bases 173 to 643 of SEQ ID NO:3.

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Claim 96 (Withdrawn) The polynucleotide of claim 95, wherein said DNA molecule comprises bases 116 to 643 of SEQ ID NO:3.

Claim 97 (Withdrawn) The polynucleotide of claim 96, wherein said DNA molecule comprises SEQ ID NO:3.

Claim 98 (Withdrawn) The polynucleotide of claim 91, wherein said *Neisseria* surface protein is encoded by a DNA molecule that comprises bases 265 to 732 of SEQ ID NO:5.

Claim 99 (Withdrawn) The polynucleotide of claim 98, wherein said DNA molecule comprises bases 208 to 732 of SEQ ID NO:5.

Claim 100 (Withdrawn) The polynucleotide of claim 99, wherein said DNA molecule comprises SEQ ID NO:5.

Claim 101 (Withdrawn) The polynucleotide of claim 91, wherein said *Neisseria* surface protein is encoded by a DNA molecule that comprises 298 to 765 of SEQ ID NO:7.

Claim 102 (Withdrawn) The polynucleotide of claim 101, wherein said DNA molecule comprises 241 to 765 of SEQ ID NO:7.

Claim 103 (Withdrawn) The polynucleotide of claim 102, wherein said DNA molecule comprises SEQ ID NO:7.

Claim 104 (Withdrawn) An isolated polynucleotide comprising bases 200 to 667 of SEQ ID NO:1.

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Claim 105 (Withdrawn) The isolated polynucleotide according to claim 104, comprising bases 143 to 667 of SEQ ID NO:1.

Claim 106 (Withdrawn) The isolated polynucleotide according to claim 105, comprising SEQ ID NO:1.

Claim 107 (Withdrawn) An isolated polynucleotide comprising bases 173 to 643 of SEQ ID NO:3.

Claim 108 (Withdrawn) The isolated polynucleotide according to claim 107, comprising bases 116 to 643 of SEQ ID NO:3.

Claim 109 (Withdrawn) The isolated polynucleotide according to claim 108, comprising SEQ ID NO:3.

Claim 110 (Withdrawn) An isolated polynucleotide comprising bases 265 to 732 of SEQ ID NO:5.

Claim 111 (Withdrawn) The isolated polynucleotide according to claim 110, comprising bases 208 to 732 of SEQ ID NO:5.

Claim 112 (Withdrawn) The isolated polynucleotide according to claim 111, comprising SEQ ID NO:5.

Claim 113 (Withdrawn) An isolated polynucleotide comprising bases 298 to 765 of SEQ ID NO:7.

Claim 114 (Withdrawn) The isolated polynucleotide according to claim 113, comprising bases 241 to 765 of SEQ ID NO:7.

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Claim 115 (Withdrawn) The isolated polynucleotide according to claim 114, comprising SEQ ID NO:7.

Claim 116 (Withdrawn) A recombinant DNA molecule, comprising (i) a polynucleotide that hybridizes under stringent conditions to said complement of claim 91 and (ii) an expression control sequence operatively linked to said polynucleotide.

Claim 117 (Withdrawn) The recombinant DNA molecule of claim 116, wherein said expression control sequence comprises an inducible expression control sequence.

Claim 118 (Withdrawn) The recombinant DNA molecule of claim 117, wherein said inducible expression control sequence is inducible by a stimulus selected from the group consisting of temperature, lactose, and IPTG.

Claim 119 (Withdrawn) The recombinant DNA molecule of claim 117, wherein said inducible expression control sequence is selected from the group consisting of λ PL, λ PR, TAC, T7, T3, LAC, and TRP promoters.

Claim 120 (Withdrawn) The recombinant DNA molecule of claim 116, wherein said DNA molecule is selected from the group consisting of pNP2202, pNP2203, and pNP2204.

Claim 121 (Withdrawn) A unicellular host transformed with the recombinant DNA molecule of claim 116.

Claim 122 (Withdrawn) The unicellular host of claim 121, wherein said host is selected from the group consisting of strains of *E.coli* JM109, *E.coli* BL21 (DE3), *E.coli* DH5 α F'IQ, *Ecoli* W3110, *E.coli* JM105, *E.coli* BL21, *Ecoli* TOPP1, *E.coli* TOPP2, and *E.coli* TOPP3.

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Claim 123 (Withdrawn) A method for producing the polynucleotide of claim 91, comprising the steps of culturing the unicellular host of claim 121 and isolating said polynucleotide.

Claim 124 (currently amended) An isolated polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to the complement of a DNA sequence encoding a *Neisseria* surface protein, wherein said *Neisseria* surface protein:

- (i) is resistant to proteinase K, and
- (ii) has an apparent molecular weight of 22 kDa, and
- (iii) is stained by Coomassie blue,
wherein said polypeptide is antigenic.

Claim 125 (currently amended) The isolated polypeptide of claim 124, wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:2.

Claim 126 (withdrawn) The isolated polypeptide of claim 124, comprising a sequence selected from the group of sequences consisting of SEQ ID NO:9; SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, and SEQ ID NO:26.

Claim 127 (previously presented) The isolated polypeptide of claim 124, comprising amino acids 31 to 55 of SEQ ID NO:2 and which is antigenic.

Claim 128 (previously presented) The isolated polypeptide of claim 124, comprising amino acids 51 to 86 of SEQ ID NO:2 and which is antigenic.

Claim 129 (previously presented) The isolated polypeptide of claim 124, comprising amino acids 110 to 140 of SEQ ID NO:2 and which is antigenic.

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Claim 130 (cancelled)

Claim 131 (withdrawn) A method of isolating the polypeptide of claim 124, comprising:

- a) isolating a culture of *Neisseria meningitidis* bacteria;
- b) isolating an outer membrane portion from said culture; and
- c) isolating said antigen from said outer membrane portion.

Claim 132 (withdrawn) The method according to claim 131, further comprising treating said outer membrane with proteinase K.

Claim 133 (previously presented) A pharmaceutical composition comprising the polypeptide of claim 124.

Claim 134 (previously presented) The pharmaceutical composition of claim 133, which is a vaccine.

Claim 135 (previously presented) The pharmaceutical composition of claim 134, comprising a pharmaceutical excipient.

Claim 136 (previously presented) A method of preventing infection by a *Neisseria* pathogen, comprising administering an effective amount of the vaccine of claim 134.

Claim 137 (previously presented) The method according to claim 136, wherein said pathogen is a *Neisseria meningitidis*.

Claim 138 (withdrawn) An antibody or a fragment thereof that specifically binds to the polypeptide of claim 124.

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Claim 139 (withdrawn) The antibody of claim 138, wherein said polypeptide is a *Neisseria* 22 kDa surface protein.

Claim 140 (withdrawn) The antibody of claim 139, wherein said *Neisseria* 22 kDa surface protein is a *Neisseria meningitidis* 22 kDa surface protein.

Claim 141 (withdrawn) The antibody of claim 138, which is a monoclonal antibody.

Claim 142 (withdrawn) The antibody of claim 141, which is of murine origin.

Claim 143 (withdrawn) The antibody of claim 142, which is an IgG isotype.

Claim 144 (withdrawn) The antibody of claim 141, which is selected from the group consisting of Me-1, Me-2, Me-3, Me-5, Me-6, and Me-7.

Claim 145 (withdrawn) A method for isolating the antibody of claim 138, comprising:

- a) introducing a preparation of a *Neisseria* organism into a mammal; and
- b) isolating a serum from the mammal containing said antibody.

Claim 146 (withdrawn) The method according to claim 145, wherein said *Neisseria* organism is *Neisseria meningitidis*.

Claim 147 (withdrawn) A method for isolating the monoclonal antibody of claim 141, comprising,

- a) introducing a preparation of a *Neisseria* organism to antibody producing cells of a mammal;
- b) fusing said cells with myeloma cells to form hybridoma cells; and
- c) isolating said monoclonal antibody from said hybridoma cells.

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Claim 148 (withdrawn) The method according to claim 147, wherein said *Neisseria* organism is *Neisseria meningitidis*.

Claim 149 (withdrawn) A pharmaceutical composition comprising the antibody or fragment thereof of claim 138.

Claim 150 (withdrawn) The pharmaceutical composition of claim 149, which is a vaccine.

Claim 151 (withdrawn) The pharmaceutical composition of claim 149, comprising a pharmaceutical excipient.

Claim 152 (withdrawn) The pharmaceutical composition according to claim 149, wherein said antibody is selected from the group consisting of Me-1 and Me-7.

Claim 153 (withdrawn) A method for treating a patient infected with a *Neisseria* pathogen, comprising administering an effective amount of any one of the pharmaceutical composition of claim 149.

Claim 154 (withdrawn) The method according to claim 153, wherein said pathogen is *Neisseria meningitidis*.

Claim 155 (withdrawn) A method for detection of a *Neisseria* antigen in a biological sample, comprising:

- a) isolating a biological sample from a patient;
- b) incubating the antibody of claim 138 with said biological sample; and
- c) detecting antibody specifically bound to the antigen.

Claim 156 (withdrawn) The method according to claim 155, wherein said pathogen is a *Neisseria meningitidis*.

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Claim 157 (withdrawn) The method according to claim 155, wherein said antibody is selected from the group consisting of Me-1 and Me-7.

Claim 158 (withdrawn) A method for detection of an antibody specific to a *Neisseria* antigen in a biological sample, comprising:

- a) isolating a biological sample from a patient;
- b) incubating the antigen of claim 124 with said the biological sample; and
- c) detecting antigen specifically bound to the antibody.

Claim 159 (withdrawn) The method according to claim 158, wherein said antigen is a *Neisseria meningitidis* antigen.

Claim 160 (withdrawn) The method according to claim 159, wherein said antigen is a *Neisseria meningitidis* 22 kDa surface protein.

Claim 161 (withdrawn) A method for detection of a *Neisseria* pathogen in a patient, comprising:

- a) labeling the antibody of claim 138 with a detectable label;
- b) administering the labeled antibody to said patient; and
- c) detecting labeled antibody specifically bound to the pathogen.

Claim 162 (withdrawn) The method according to claim 161, wherein said pathogen is *Neisseria meningitidis*.

Claim 163 (withdrawn) A method for detection of *Neisseria* bacteria in a biological sample, comprising,

- a) isolating a biological sample from a patient;
- b) contacting said sample with a DNA probe that is capable of hybridizing under stringent conditions with a polynucleotide encoding a *Neisseria* surface protein according to claim 91; and

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c) detecting hybridization by said DNA probe to said polynucleotide.

Claim 164 (withdrawn) The method according to claim 163, wherein said DNA probe comprises the polynucleotide of claim 94.

Claim 165 (withdrawn) The method according to claim 163, wherein said DNA probe comprises the polynucleotide of claim 97.

Claim 166 (withdrawn) The method according to claim 163, wherein said DNA probe comprises the polynucleotide of claim 100.

Claim 167 (withdrawn) The method according to claim 163, wherein said DNA probe comprises the polynucleotide of claim 103.

Claim 168 (withdrawn) The method according to claim 163, wherein said DNA probe is an oligomer having a sequence complementary to at least 6 contiguous nucleotides of the polynucleotide of claim 91.

Claim 169 (withdrawn) The method according to claim 163, further comprising a step of amplifying a target DNA by polymerase chain reaction with a set of oligomers having a sequence (i) complementary to at least 6 contiguous nucleotides of the polynucleotide of claim 91 and (ii) flanking said target DNA.

Claim 170 (previously presented) The vaccine of claim 134, which further comprises an adjuvant.

Claim 171 (previously presented) The vaccine of claim 170, wherein the adjuvant is a liposome adjuvant.

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Claim 172 (previously presented) The method of claim 136, wherein the vaccine further comprises an adjuvant.

Claim 173 (previously presented) The method of claim 172, wherein the adjuvant is a liposome adjuvant.

Claim 174 (currently amended) An isolated polypeptide from the surface of *Neisseria* bacteria which

- (i) is resistant to proteinase K, and
 - (ii) has an apparent molecular weight of 22 kDa, and
 - (iii) is stained by Coomassie blue, and
- wherein said polypeptide is antigenic.

Claim 175 (previously presented) The isolated polypeptide of claim 174, wherein said polypeptide comprises the amino acid sequence of SEQ ID NO:2.

Claim 176 (previously presented) The isolated polypeptide of claim 124, wherein said polypeptide consists of the amino acid sequence of SEQ ID NO:2.

Claim 177 (previously presented) The isolated polypeptide of claim 124, consisting of amino acids 51 to 86 of SEQ ID NO:2 and which is antigenic.

Claim 178 (previously presented) The isolated polypeptide of claim 124, comprising amino acids 110 to 140 of SEQ ID NO:2 and which is antigenic.

Claim 179 (previously presented) The isolated polypeptide of claim 124, consisting of amino acids 31 to 55 of SEQ ID NO. 2 and which is antigenic.

Claim 180 (previously presented) The isolated polypeptide of claim 124 having an antigenicity effective for use as a vaccine.

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Claim 181 (previously presented) The isolated polypeptide of claim 174 having an antigenicity effective for use as a vaccine.

Claim 182 (new) An isolated polypeptide of claim 124, wherein said polypeptide is capable of eliciting antibodies that are specific to said polypeptide

Claim 183 (new) An isolated polypeptide of claim 124, wherein said polypeptide is capable of eliciting bacteriolytic antibodies against *Neisseria meningitidis*.

Claim 184 (new) An isolated polypeptide of claim 174, wherein said polypeptide is capable of eliciting antibodies that are specific to said polypeptide

Claim 185 (new) An isolated polypeptide of claim 174, wherein said polypeptide is capable of eliciting bacteriolytic antibodies against *Neisseria meningitidis*.

Claim 186 (new) An isolated polypeptide of claim 124, wherein said hybridizing is at 42°C with a solution comprising 50% formamide.

Claim 187 (new) An isolated polypeptide of claim 124, which is free of any other *Neisseria meningitidis* polypeptide.

Claim 188 (new) A composition comprising an isolated polypeptide of claim 187, and a pharmaceutically acceptable excipient.

Claim 189 (new) An isolated polypeptide of claim 174, which is free of any other *Neisseria meningitidis* polypeptide.

Claim 190 (new) A composition comprising an isolated polypeptide of claim 189, and a pharmaceutically acceptable excipient.

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Claim 191 (new) A vaccine, comprising a polypeptide of claim 187 and an adjuvant.

Claim 192 (new) A method of manufacturing a vaccine, comprising
formulating a polypeptide of claim 187 with an adjuvant.

Claim 193 (new) A vaccine, comprising a polypeptide of claim 190 and an adjuvant.

Claim 194 (new) A method of manufacturing a vaccine, comprising
formulating a polypeptide of claim 189 with an adjuvant.

Claim 195 (new) An isolated polypeptide of claim 124, wherein said polypeptide is
produced recombinantly.

Claim 196 (new) An isolated polypeptide of claim 174, wherein said polypeptide is
produced recombinantly.